

antibody-binding pocket. If chelates are bound to the Fab but not covalently linked, they dissociate because the antibody-binding pocket holding them together is no longer folded. Unbound chelate does not migrate with the antibody chains. However, chelate which bound to a Fab and then covalently linked, will be attached to the Fab light chain and migrate with it on SDS-PAGE. This result was observed with the Fab S95C (ATCC Deposit No. PTA-4695, made September 19, 2002 at the ATCC, 10801 University Blvd. Manassas, VA 20110-2209)(FIG. 18).

REMARKS

Rejections under 35 U.S.C. § 112, First Paragraph

Claim 14 stands rejected under 35 U.S.C. § 112, first paragraph, as being allegedly non-enabled. The Examiner states that the specification does not provide evidence that the claimed biological materials are (1) known and readily available to the public) or (2) reproducible from the written description. In making the rejection, the Examiner states that a deposit of the hybridoma would satisfy the enablement requirements of 35 U.S.C. § 112, first paragraph. Claim 14 recites "wherein said mutant antibody is a mutant of CHA255."

The cell line expressing the S95C antibody, a mutant of the CHA255 antibody, has been deposited with the ATCC in accordance with the provisions of the Budapest Treaty. Applicants have also amended the specification at page 74, line 33 to state that the deposit was made on September 19, 2002 at the ATCC, 10801 University Blvd. Manassas, VA 20110-2209. The following documents in support of the deposit are enclosed:

1. A marked up copy of the amended paragraph (Appendix A).
2. A true copy of the completed deposit form (Appendix B).
3. A statement under 37 C.F.R. § 1.808 from the assignee, the Regents of the University of California, confirming that all restrictions imposed by Regents of the University of California on the availability to the public of the aforementioned deposited

material will be irrevocably removed upon the granting of a patent for the above-referenced patent application (Appendix C).

4. A verified statement under 37 C.F.R. § 1.804 from Dr. Albert Chmura stating that the deposited material is identical to the biological material described in the specification (Appendix D).


Since a deposit has been made, Applicants respectfully request withdrawal of the rejection of claim 14 under 35 U.S.C. § 112, first paragraph.

CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 415-576-0200.

Respectfully submitted,



Carol A. Fang
Reg. No. 48,631

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APPENDIX A

VERSION WITH MARKINGS TO SHOW CHANGES MADE

IN THE SPECIFICATION

On page 74, lines 26-33, please insert the following replacement paragraph:

The samples were analyzed by SDS-PAGE and visualized by phosphorimager. Separation under reducing and denaturing conditions on SDS-PAGE will separate the light chain from the heavy chain of each Fab, functionally destroying the antibody-binding pocket. If chelates are bound to the Fab but not covalently linked, they dissociate because the antibody-binding pocket holding them together is no longer folded. Unbound chelate does not migrate with the antibody chains. However, chelate which bound to a Fab and then covalently linked, will be attached to the Fab light chain and migrate with it on SDS-PAGE. This result was observed with the Fab S95C (ATCC Deposit No. PTA-4695, made September 19, 2002, at the ATCC, 10801 University Blvd. Manassas, VA 20110-2209) (**FIG. 18**).

**BUDAPEST TREATY ON THE INTERNATIONAL RECOGNITION OF
THE DEPOSIT OF MICROORGANISMS FOR THE PURPOSES OF PATENT PROCEDURE**

INTERNATIONAL FORM

**RECEIPT IN THE CASE OF AN ORIGINAL DEPOSIT ISSUED PURSUANT TO RULE 7.3
AND VIABILITY STATEMENT ISSUED PURSUANT TO RULE 10.**

To: (Name and Address of Depositor or Attorney)

University of California
Attn: A.J. Chmura, PhD
100 North First Street
Dixon, California 95620

Deposited on Behalf of: University of California

Identification Reference by Depositor:

Drosophila Melanogaster: CHA cFab S95C
Drosophila Melanogaster: CHA cFab Nat

Patent Deposit Designation

PTA-4695
PTA-4696

The deposits were accompanied by: a scientific description a proposed taxonomic description indicated above. The deposits were received September 19, 2002 by this International Depository Authority and have been accepted.

AT YOUR REQUEST: X We will inform you of requests for the strains for 30 years.

The strains will be made available if a patent office signatory to the Budapest Treaty certifies one's right to receive, or if a U.S. Patent is issued citing the strains, and ATCC is instructed by the United States Patent & Trademark Office or the depositor to release said strains.

If the cultures should die or be destroyed during the effective term of the deposit, it shall be your responsibility to replace them with living cultures of the same.

The strains will be maintained for a period of at least 30 years from date of deposit, or five years after the most recent request for a sample, whichever is longer. The United States and many other countries are signatory to the Budapest Treaty.

The viability of the cultures cited above was tested September 26, 2002. On that date, the cultures were viable.

International Depository Authority: American Type Culture Collection, Manassas, VA 20110-2209 USA.

Signature of person having authority to represent ATCC:

Marie Harris
Marie Harris, Patent Specialist, ATCC Patent Depository

Date: October 10, 2002

cc: Jeffry S. Mann
(Ref: Docket or Case No.: UC 2000-123 (23070-0990US))

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to:

PATENT
Attorney Docket No.: 02307O-099120US
Client Ref. No.: 2000-123-3

Assistant Commissioner for Patents
Washington, D.C. 20231

On Oct. 21, 2002

TOWNSEND and TOWNSEND and CREW LLP

By: Patricia Andrus

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Claude F. Meares, et al.

Application No.: 09/671,953

Filed: September 27, 2000

For: ENGINEERING ANTIBODIES
THAT BIND IRREVERSIBLY

Examiner: Larry R. Helms

Art Unit: 1642

STATEMENT UNDER 37 C.F.R. § 1.808

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

The above-referenced patent application refers to the following biological deposits:

ATCC PTA-4695: *Drosophila* Cell Line

ATCC PTA-4696: *Drosophila* Cell Line

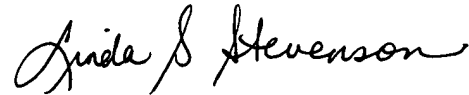
These deposits were made pursuant to the Budapest Treaty. A Deposit Receipt and Viability Statement is attached hereto as Appendix A.

Claude F. Meares, et al.
Application No.: 09/671,953
Page 2

PATENT

Assignee, the Regents of the University of California, by its undersigned agent, hereby confirms that, subject to paragraph (b) of 37 C.F.R. § 1.808, all restrictions imposed by Regents of the University of California on the availability to the public of the aforementioned deposited material will be irrevocably removed upon the granting of a patent for the above-referenced patent application.

Respectfully submitted,

A handwritten signature in cursive script that reads "Linda S. Stevenson".

Linda Stevenson
Manager, Patent Prosecution
Regents of the University of
California

TOWNSEND and TOWNSEND and CREW LLP
Two Embarcadero Center, 8th Floor
San Francisco, California 94111-3834
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SF 1380209 v1

ATCC

10801 University Blvd • Manassas, VA 20110-2209 • Telephone: 703-365-2700 • FAX: 703-365-2745

**BUDAPEST TREATY ON THE INTERNATIONAL RECOGNITION OF
THE DEPOSIT OF MICROORGANISMS FOR THE PURPOSES OF PATENT PROCEDURE****INTERNATIONAL FORM****RECEIPT IN THE CASE OF AN ORIGINAL DEPOSIT ISSUED PURSUANT TO RULE 7.3
AND VIABILITY STATEMENT ISSUED PURSUANT TO RULE 10.**

To: (Name and Address of Depositor or Attorney)

University of California
Attn: A.J. Chmura, PhD
100 North First Street
Dixon, California 95620

Deposited on Behalf of: University of California

Identification Reference by Depositor:

Patent Deposit Designation

Drosophila Melanogaster: CHA cFab S95C
Drosophila Melanogaster: CHA cFab NatPTA-4695
PTA-4696

The deposits were accompanied by: a scientific description, a proposed taxonomic description indicated above. The deposits were received September 19, 2002 by this International Depository Authority and have been accepted.

AT YOUR REQUEST: ☒ We will inform you of requests for the strains for 30 years.

The strains will be made available if a patent office signatory to the Budapest Treaty certifies one's right to receive, or if a U.S. Patent is issued citing the strains, and ATCC is instructed by the United States Patent & Trademark Office or the depositor to release said strains.

If the cultures should die or be destroyed during the effective term of the deposit, it shall be your responsibility to replace them with living cultures of the same.

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International Depository Authority: American Type Culture Collection, Manassas, VA 20110-2209 USA.

Signature of person having authority to represent ATCC:

Marie Harris
Marie Harris, Patent Specialist, ATCC Patent DepositoryDate: October 10, 2002

cc: Jeffry S. Mann

(Ref: Docket or Case No.: UC 2000-123 (23070-0990US))

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to:

PATENT
Attorney Docket No.: 023070-099120US
Client Ref. No.: 2000-123-3

Assistant Commissioner for Patents
Washington, D.C. 20231

On Oct. 21, 2002

TOWNSEND and TOWNSEND and CREW LLP

By: Patricia Andrews

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Claude F. Meares, et al.

Application No.: 09/671,953

Filed: September 27, 2000

For: ENGINEERING ANTIBODIES
THAT BIND IRREVERSIBLY

Examiner: Larry R. Helms

Art Unit: 1642

STATEMENT UNDER 37 C.F.R. § 1.804

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

I am a named inventor on the above-referenced patent application.

The above-referenced patent application refers to the following biological deposits:

ATCC PTA-4695: *Drosophila* Cell Line

ATCC PTA-4696: *Drosophila* Cell Line

These deposits were made pursuant to the Budapest Treaty. A Deposit Receipt and Viability Statement is attached hereto as Appendix A.

Claude F. Meares, et al.
Application No.: 09/671,953
Page 2

PATENT

I hereby confirm that, subject to paragraph (b) of 37 C.F.R. §1.804, the deposited material is identical to the biological material described in the specification as filed.

Respectfully submitted,



Albert J. Chmura, Ph.D.

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**BUDAPEST TREATY ON THE INTERNATIONAL RECOGNITION OF
THE DEPOSIT OF MICROORGANISMS FOR THE PURPOSES OF PATENT PROCEDURE****INTERNATIONAL FORM****RECEIPT IN THE CASE OF AN ORIGINAL DEPOSIT ISSUED PURSUANT TO RULE 7.3
AND VIABILITY STATEMENT ISSUED PURSUANT TO RULE 10.****To: (Name and Address of Depositor or Attorney)**University of California
Attn: A.J. Chmura, PhD
100 North First Street
Dixon, California 95620

Deposited on Behalf of: University of California

Identification Reference by Depositor:Drosophila Melanogaster: CHA cFab S95C
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Marie Harris
Marie Harris, Patent Specialist, ATCC Patent Depository

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